

K073406

**510(k) SUMMARY**

JAN 23 2008

**VITEK® 2 Gram Negative Trimethoprim/sulfamethoxazole****510(k) Submission Information:**

Submitter's Name: bioMérieux, Inc.  
Address: 595 Anglum Road  
Hazelwood, MO 63042  
Contact Person: Nancy Weaver  
Associate Director, Regulatory Affairs  
Phone Number: 314-731-8695  
Fax Number: 314-731-8689  
Date of Preparation: November 29, 2007

**B. Device Name:**

Formal/Trade Name: VITEK® 2 Gram Negative  
Trimethoprim/sulfamethoxazole  
( $\leq$  1/19 –  $\geq$  16/304  $\mu$ g/ml)  
Classification Name: Fully Automated Short-Term Incubation Cycle  
Antimicrobial Susceptibility Device, 21 CFR 866.1645  
Common Name: VITEK 2 AST-GN SXT

**C. Predicate Device:** VITEK 2 Gram Negative Ertapenem (K041982).

**D. 510(k) Summary:**

VITEK® 2 Gram Negative Trimethoprim/sulfamethoxazole is designed for antimicrobial susceptibility testing of *Escherichia coli*, *Klebsiella* sp., *Enterobacter* sp., *Morganella morganii*, *Proteus mirabilis*, *Proteus vulgaris*, *Shigella flexneri* and *Shigella sonnei*. VITEK 2 Gram Negative Trimethoprim/Sulfamethoxazole is a quantitative test. It is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. The antimicrobial presented in VITEK 2 AST Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The VITEK 2 AST Cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The bacterial isolate to be tested is diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 System automatically fills, seals and places the card into the incubator/reader. The VITEK 2 Compact has a manual filling and sealing operation. The VITEK 2 monitors the growth of each well in the card over a defined period of time (up to 18 hours). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antibiotic contained on the card.

**bioMérieux, Inc.**

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VITEK 2 Gram Negative Trimethoprim/sulfamethoxazole demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA, Issued Feb. 5, 2003. \*

The Premarket Notification (510[k]) presents data in support of VITEK 2 Gram Negative Trimethoprim/sulfamethoxazole. An external evaluation was conducted with fresh and stock clinical isolates and stock challenge strains. The external evaluations were designed to confirm the acceptability of VITEK 2 Gram Negative Trimethoprim/sulfamethoxazole by comparing its performance with the CLSI broth microdilution reference method. The data is representative of performance on both the VITEK 2 and VITEK 2 Compact instrument platforms, as evidenced in the AST equivalency study presented in the VITEK 2 Compact 510(k), K050002. VITEK 2 Gram Negative Trimethoprim/sulfamethoxazole demonstrated acceptable performance of 100% overall Category Agreement. Reproducibility and Quality Control demonstrated acceptable results.

\*Note: This device clinical trial was initiated prior to the March 5, 2007 issuance of the revised guidance, which is why the earlier guidance document is cited.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JAN 23 2008

Ms. Nancy Weaver  
Associate Director, Regulatory Affairs  
bioMérieux, Inc.  
595 Anglum Road  
Hazelwood, MO 63042

Re: k073406

Trade/Device Name: VITEK 2<sup>®</sup> Gram Negative Trimethoprim/sulfamethoxazole ( $\leq 1/19$   
– 16/304  $\mu\text{g}/\text{ml}$ )

Regulation Number: 21 CFR 866.1645

Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial  
Susceptibility Device

Regulatory Class: Class II

Product Code: LON

Dated: November 29, 2007

Received: December 4, 2007

Dear Ms. Weaver:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

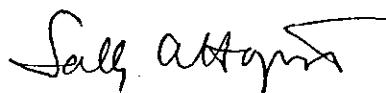
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K07 3406

Device Name: VITEK® 2 Gram Negative Trimethoprim/sulfamethoxazole  
( $\leq 1/19$  –  $\geq 16/304$   $\mu\text{g/ml}$ )

### Indication For Use:

VITEK® 2 Gram Negative Trimethoprim/sulfamethoxazole is designed for antimicrobial susceptibility testing of gram-negative organisms and is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK 2 Gram Negative Trimethoprim/sulfamethoxazole is a quantitative test. Trimethoprim/sulfamethoxazole has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

#### Active *in vitro* and in clinical infections

*Escherichia coli* (including susceptible enterotoxigenic strains implicated in traveler's diarrhea)  
*Klebsiella* species                            *Proteus mirabilis*  
*Enterobacter* species                        *Shigella flexneri*  
*Morganella morganii*                        *Shigella sonnei*  
*Proteus vulgaris*

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 and VITEK® 2 Compact Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus* spp., *Enterococcus* spp., *Streptococcus agalactiae*, and *S. pneumoniae*.

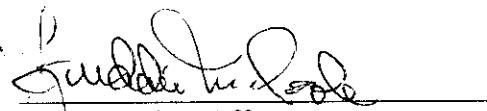
Prescription Use X  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use         
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

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